

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA**

**ALLERGAN, INC. and DUKE
UNIVERSITY,**

Plaintiffs,

Case No. 1:10-CV-681

v.

APOTEX INC. and APOTEX CORP.,

Defendants.

**ALLERGAN, INC. and DUKE
UNIVERSITY,**

Plaintiffs,

Case No. 1:11-CV-298

v.

SANDOZ INC.,

Defendant.

**ALLERGAN, INC. and DUKE
UNIVERSITY,**

Plaintiffs,

Case No. 1:11-CV-650

v.

HI-TECH PHARMACAL CO., INC.,

Defendant.

**ALLERGAN, INC. and DUKE
UNIVERSITY,**

Case No. 1:12-CV-321

Plaintiffs,

v.

**ACTAVIS, INC., WATSON
LABORATORIES, INC., and WATSON
PHARMA, INC.,**

Defendant.

**DEFENDANTS APOTEX, SANDOZ, HI-TECH, AND ACTAVIS'S BRIEF IN
OPPOSITION TO PLAINTIFFS ALLERGAN AND DUKE'S
MOTION FOR A PERMANENT INJUNCTION**

Defendants Apotex Inc., Apotex Corp., Sandoz Inc., Hi-Tech Pharmacal Co., Inc., Watson Pharmaceuticals, Inc., n/k/a Actavis, Inc., Watson Laboratories, Inc., and Watson Pharma, Inc. (Watson entities collectively, "Actavis") (all defendants collectively, "Defendants") respectfully submit this Brief in Opposition to Plaintiffs' Motion for a Permanent Injunction (10-cv-681 Doc. 211, 12-cv-321 Doc. 58).

INTRODUCTION

Well after judgment was entered in the above-captioned cases and the cases were closed, Plaintiffs Allergan, Inc. ("Allergan") and Duke University ("Duke") (collectively, "Plaintiffs") have filed a motion seeking permanent injunctive relief against Defendants in these closed cases based on assertions that were never proven at trial, and based on assertions from one witness—Ralph L. McCaughan¹—who was never disclosed in Plaintiffs' Rule 26(a)(1) disclosures, never deposed, never identified in Plaintiffs' Rule 26(a)(3)(A) pretrial disclosures as a witness Plaintiffs would or may call to testify at trial, never called to testify at trial, and never cross-examined. Moreover, the allegations

¹ See Pls. Br. in Supp. of Their Mot. for a Permanent Injunction ("Pls.' Br.") Ex. D, Decl. of Ralph McCaughan in Supp. of Pls.' Mot. for a Permanent Injunction ("McCaughan Decl.").

underlying Plaintiffs' Motion were never presented to this Court in Plaintiffs' proposed findings of fact or conclusions of law, and this Court never issued any findings on the facts Plaintiffs allege in support of their Motion or any conclusions of law concerning the injunctive relief Plaintiffs seek.

As explained further below, entry of a permanent injunction under these circumstances, where the above-captioned cases are closed and where Defendants never had any opportunity to secure discovery on the factual allegations underlying Plaintiffs' Motion or depose or cross-examine Plaintiffs' declarants, would violate Defendants' Fifth Amendment guarantee of procedural due process, and would also violate Federal Rule of Civil Procedure 52, which requires this Court to issue findings of fact and conclusions of law supporting its Judgment and the relief Plaintiffs seek.

In light of the foregoing, explained more fully below, Plaintiffs' Motion should be denied without even reaching its merits. However, even if this Court somehow reaches the merits of Plaintiffs' Motion despite its Constitutional and procedural infirmities, Plaintiffs' Motion should still be denied because they have failed as a matter of law to prove the four factors required for a permanent injunction.

BACKGROUND

Trial in the above-captioned matters concluded on November 20, 2012. Initial post-trial briefs and proposed findings of fact and conclusions of law were filed on December 10, 2012, and responsive post-trial briefs were filed on December 21, 2012. (See, e.g., 10-cv-681 Docs. 190-91, 199).

On January 24, 2013, this Court issued its Memorandum Opinion and Order which included the Court’s “findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(a).” (10-cv-681 Doc. 208 at 2). On January 25, 2013, this Court entered its Judgment in favor of Plaintiffs with respect to their claims of infringement involving U.S. Patent Nos. 7,388,029 (“the ‘029 patent”) and 7,351,404 (“the ‘404 patent”) and in favor of Plaintiffs and against Defendants with respect to Defendants’ invalidity claims. (10-cv-681 Doc. 209). With respect to Actavis, the Court entered Judgment on February 4, 2013 in the 12-cv-321 case regarding the ‘404 and ‘029 patents, which were severed from that case (12-cv-321 Doc. 56). The civil actions were terminated the day Judgment was entered in each case.²

Three weeks after Judgment was entered and the consolidated 10-cv-681 actions were terminated, Plaintiffs filed the instant Motion seeking a permanent injunction against Defendants. (10-cv-681 Doc. 211). Plaintiffs’ Motion was filed with two supporting declarations, one from Robert Rhatigan, an Allergan employee,³ and one from Ralph L. McCaughan, a Duke employee.⁴

² Regarding Actavis, the Court severed the ‘404 and ‘029 patents from Case 12-cv-321, and that case was terminated with respect to these patents on entry of judgment in the case regarding those patents (12-cv-321 Doc. 56). The case pertaining to related patents remains pending in connection with consolidated Case 12-cv-247 (12-cv-321 Doc. 44).

³ Pls.’ Br. Ex. A, Decl. of Robert Rhatigan in Supp. of Pls.’ Mot. for a Permanent Injunction (“Rhatigan Decl.”).

⁴ Pls.’ Br. Ex. D, McCaughan Decl.

Mr. McCaughan was never disclosed in Plaintiffs' Rule 26(a)(1) disclosures;⁵ as such, Mr. McCaughan was never deposed. Moreover, Messrs. Rhatigan and McCaughan never served expert reports pursuant to Rule 26(a)(2)(B). Further, Mr. McCaughan was never disclosed in Plaintiffs' Rule 26(a)(3) pretrial disclosures as a witness Plaintiffs would or may call to testify at trial (10-cv-681 Doc. 156), nor was Mr. McCaughan ever called to testify at trial or cross-examined.

Finally, the assertions set forth in the Rhatigan and McCaughan declarations supporting alleged irreparable harm are essentially missing from Plaintiffs' Proposed Findings of Fact and Conclusions of Law.⁶ Nor did this Court issue any findings concerning the allegations set forth in the Rhatigan and McCaughan declarations in its Memorandum Opinion and Order. (10-cv-681 Doc. 208).

ARGUMENT

I. PLAINTIFFS' MOTION SEEKS RELIEF THAT WOULD VIOLATE DEFENDANTS' PROCEDURAL DUE PROCESS RIGHTS.

Defendants have a Constitutional right to not be "deprived of . . . liberty . . . without due process of law." U.S. CONST. AMEND. V. "The fundamental requisite of due process of law is the opportunity to be heard." *Goldberg v. Kelly*, 397 U.S. 254, 267 (1970) (internal quotations and citations omitted). Moreover, "[i]n almost every setting where important decisions turn on questions of fact, due process requires an opportunity

⁵ See Decl. of Timothy F. Peterson, Esq., ("Peterson Decl.") Ex. A, Pls.' Initial Disclosures Pursuant to Fed. R. Civ. P. 26(a)(1); *id.* at Ex. B, Pls.' Supplemental Initial Disclosures Pursuant to Fed. R. Civ. P. 26(a)(1); *id.* at Ex. C, Pls.' Second Supplemental Initial Disclosures Pursuant to Fed. R. Civ. P. 26(a)(1).

⁶ See Oct. 15, 2012 Pls.' Proposed Findings of Fact and Conclusions of Law; Dec. 10, 2012 Pls.' Proposed Findings of Fact and Conclusions of Law.

to confront and cross-examine adverse witnesses.” *Id.* at 269; *see also* *Derewecki v. Pa. R.R. Co.*, 353 F.2d 436, 442 (3d Cir. 1965) (“[T]he right of cross-examination inheres in every adversary proceeding and that it is established beyond any necessity for citation of authorities . . . that if cross examination of an available witness is not had the litigant, deprived of cross-examination, has been denied due process of law.”); *Carter v. Morehouse Parish Sch. Bd.*, 441 F.2d 380, 382 (5th Cir. 1971) (“A ruling based on evidence which a party has not been allowed to confront or rebut is one which denies due process.”).

The permanent injunctive relief Plaintiffs seek here would clearly violate Defendants’ Fifth Amendment procedural due process rights. As explained above, Plaintiffs’ Motion is based on a declaration from a witness, Mr. McCaughan, who was never identified in Plaintiffs’ Rule 26(a)(1) disclosures as a witness with discoverable information; as such, Defendants never had an opportunity to depose Mr. McCaughan during discovery. Mr. McCaughan was never disclosed in Plaintiffs’ Rule 26(a)(3) pretrial disclosures as a witness Plaintiffs would or may call at trial, and Plaintiffs never called him to testify at trial. Simply put, Defendants were never given notice that Mr. McCaughan had discoverable information in these cases, and were denied any opportunity to confront, depose or cross-examine Mr. McCaughan and challenge him on the allegations made in his declaration.

Although Mr. Rhatigan was called to testify at trial, he never testified as to the irreparable harm allegations in his declaration, including the allegations at paragraphs 10-20. Nor were those allegations included in Plaintiffs’ Proposed Findings of Fact and

Conclusions of law submitted before trial on October 15, 2012. Thus, Defendants never had notice that Mr. Rhatigan had discoverable knowledge on irreparable harm, and never had an opportunity to cross-examine Mr. Rhatigan on the irreparable harm allegations in his declaration.⁷

The permanent injunction Plaintiffs seek against Defendants is predicated on factual allegations from witnesses Defendants never had an opportunity to confront and cross-examine. Entry of the order Plaintiffs seek would violate Defendants procedural due process rights and, thus, Plaintiffs' Motion must be denied without reaching its merits.

II. ENTRY OF THE INJUNCTION PLAINTIFFS SEEK WOULD VIOLATE FED. R. CIV. P. 52.

“In an action tried on the facts without a jury or with an advisory jury, the court must find the facts specially and state its conclusions of law separately.” FED. R. CIV. P. 52(a)(1). Rule 52 expressly requires this for interlocutory injunctions, Fed. R. Civ. P. 52(a)(2), and it is well settled that this is also a requirement for suits “in which permanent injunctions are issued,” *Alberti v. Cruise*, 383 F.2d 268, 271 (4th Cir. 1967). *See also* *Knox v. Salinas*, 193 F.3d 123, 129 (2nd Cir. 1999) (“Pursuant to Fed.R.Civ.P. 65(d), an order entering an injunction ‘shall set forth the reasons for its issuance.’” Similarly, Fed.R.Civ.P. 52(a) requires special findings of fact and conclusions of law in support of a

⁷ Defendants also note that the Rhatigan and McCaughan Declarations go beyond mere factual allegations and in fact propound expert opinions on the ultimate issue of irreparable harm in the context of Plaintiffs' motion for a permanent injunction; however, Messrs. Rhatigan and McCaughan were never disclosed as experts as required by Fed. R. Civ. P. 26(a)(2)(A) nor did they serve written reports required pursuant to Fed. R. Civ. P. 26(a)(2)(B).

permanent injunction.”); *SEC v. Mgmt. Dynamics, Inc.*, 515 F.2d 801, 814 (2nd Cir. 1975) (“We find it plain that the entry of a permanent injunction without appropriate findings violates the command of Fed.R.Civ.P. 52(a).”).⁸

Here, this Court never entered any findings of fact or conclusions of law concerning a permanent injunction in its January 24, 2013 Memorandum Opinion and Order (10-cv-681 Doc. 208)—with good reason, as Plaintiffs never proposed any findings of fact or conclusions of law concerning a permanent injunction for the Court to adopt. Nor did Plaintiffs introduce any evidence or call witnesses to testify at trial proving any facts supporting a permanent injunction, including facts establishing irreparable harm. Mr. McCaughan was never called to testify at trial, and although Mr. Rhatigan testified at trial, he never testified to the irreparable harm allegations in his declaration attached to Plaintiffs’ Motion. Thus, entry of the order Plaintiffs seek would expressly violate the mandate of Rule 52.

Furthermore, this Court cannot simply make additional findings pursuant to Rule 52(b) supporting a permanent injunction based on the Rhatigan and McCaughan declarations because, “[n]ormally, an evidentiary hearing is required before an injunction may be granted.” *United States v. McGee*, 714 F.2d 607, 613 (6th Cir. 1983); *see also Modeco Sec. Locks, Inc. v. Swiderek*, 680 F.2d 37, 38 (7th Cir. 1981) (“It is well established that, in general, a motion for a preliminary injunction should not be resolved

⁸ A district court is required to issue Rule 52 findings of fact and conclusions of law supporting entry of a permanent injunction so that the appellate court has a proper record to review on appeal. *See Dixon v. Edwards*, 290 F.3d 699, 718 (4th Cir. 2002) (“we review the [district] court’s underlying factual findings [for a permanent injunction] for clear error and its conclusions of law *de novo*”).

on the basis of affidavits alone. Normally, an evidentiary hearing is required to decide credibility issues.”). The only possible exception to this general rule is when there are no triable issues of fact. *McGee*, 714 F.2d at 613.

Here, as explained above, these cases are closed and Defendants never had an opportunity to secure discovery from Plaintiffs and Messrs. Rhatigan and McCaughan regarding the factual allegations supporting Plaintiffs’ Motion. Thus, Defendants cannot “present facts essential to justify [their] opposition,” Fed. R. Civ. P. 56(d), and this Court cannot enter additional findings of fact and conclusions of law based on the Rhatigan and McCaughan declarations, which allege facts that are nowhere in the trial record. *See Fontenot v. Mesa Petroleum Co.*, 791 F.2d 1207, 1219 (5th Cir. 1986) (“Except for motions to amend based on newly discovered evidence, the trial court is only required to amend its findings of fact based on evidence contained in the record. To do otherwise would defeat the compelling interest in the finality of litigation.”).

Plaintiffs’ Motion is not based on newly discovered evidence; in fact, the facts Plaintiffs and Messrs. Rhatigan and McCaughan allege in support of a permanent injunction were clearly available to Plaintiffs before the close of trial. Thus, Rule 52(b) is unavailable to Plaintiffs and this Court. Plaintiffs made a decision to specifically not call Messrs. Rhatigan and McCaughan to testify at trial or to otherwise prove their allegations supporting a permanent injunction. Under these circumstances, entry of the order Plaintiffs seek would violate Rule 52 and, thus, Plaintiffs’ Motion should be denied.

III. PLAINTIFFS' MOTION SHOULD BE DENIED BECAUSE THERE IS NO IRREPARABLE HARM.

The Constitutional and procedural infirmities of Plaintiffs' Motion mandate denial; however, even if somehow this Court reaches the merits of the Motion, it should still be denied. To be entitled to a permanent injunction, Plaintiffs must demonstrate:

(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006). These factors must be demonstrated in the ANDA context when a permanent injunction is sought pursuant to 35 U.S.C. § 271(e)(4)(B). *Alcon, Inc. v. Teva Pharm. USA, Inc.*, No.06-234-SLR, 2010 WL 3081327, at *2 (D. Del. Aug. 5, 2010). As explained below, if this Court somehow reaches the merits of Plaintiffs' Motion, it should be denied because Plaintiffs have failed to demonstrate the required factors.

A. There Is No Irreparable Harm.

On January 24, 2013, this Court issued an order resetting the effective approval dates of Defendants' ANDAs to the expiration of the '029 and '404 patents. (10-cv-681 Doc. 208 at 25). The Order was included in this Court's Judgment entered on January 25, 2013. (10-cv-681 Doc. 209 at 2, 12-cv-321 Doc. 56 at 2). Pursuant to the Court's Order, FDA cannot approve Defendants' ANDAs until May 25, 2024, when the '029 and '404 patents will have expired.⁹ This completely eliminates the possibility of any harm

⁹ See 12-cv-247 Doc. 77-1 at 1, 12-cv-321 Doc. 53-1 at 1.

to Plaintiffs, as it is against the law to sell a drug in interstate commerce without FDA approval. *See* 21 U.S.C. § 355(a), (b), and (j); *see also* *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000) (“[I]f [an ANDA-filer] introduces a drug into interstate commerce without complying with the approval requirements of 21 U.S.C. § 355, it is subject to various additional penalties, *see* 21 U.S.C. § 331(d), including an injunction, *see* 21 U.S.C. § 332(a), criminal sanctions, *see* 21 U.S.C. § 333(a), seizure of the unapproved drug, *see* 21 U.S.C. § 334(a)(1), and debarment of its corporation and individual officials from submitting or assisting in the submission of an ANDA in the future, *see* 21 U.S.C. § 335a.”). Thus, the entirety of Plaintiffs’ irreparable harm arguments at pages 5-11 of their Brief should be disregarded because they assume something that can never legally happen—a launch by Defendants prior to expiration of the ‘029 and ‘404 patents.

Plaintiffs’ only response to this obvious reality, which conclusively establishes that they could never be irreparably harmed if an injunction is not entered, is to speculate that the Court’s Order resetting the ANDA approval dates may not be enough because of Defendant Apotex’s conduct in *Abbott Laboratories v. Torpharm, Inc.*, 503 F.3d 1372 (Fed. Cir. 2007). But it is important to note—and telling that Plaintiffs wait until the end of their discussion of *Abbott* to address this in a footnote (Pls.’ Br. 3 n.1)—that Apotex’s conduct in *Abbott* was held perfectly legal by the Federal Circuit. *Abbott*, 503 F.3d at 1382-83. Specifically, the Federal Circuit held that the conduct complained of in *Abbott*, and the very conduct Plaintiffs speculate might arise in this case (Pls.’ Br. 2-3)—the filing of a new ANDA—did not violate the original injunction entered in *Abbott*. *Id.*

What's more, the injunction Plaintiffs propose in the instant cases would not prohibit the Apotex conduct complained of in *Abbott* because the language of the injunction proposed by Plaintiffs in the instant action mirrors the language of the original injunction in *Abbott*—*compare* Plaintiffs' [Proposed] Permanent Injunction with *Abbott*, 503 F.3d at 1376-77, 1382-83—which the Federal Circuit held did not prohibit Apotex's filing of a new ANDA. *Abbott*, 503 F.3d at 1382-83. This exposes the stated basis for Plaintiffs' Motion (Pls.' Br. 2-3) as nothing more than a feigned concern for something that will likely never happen. Simply put, Plaintiffs have failed to prove irreparable harm, which requires actual proof based on evidence and not mere speculation. *See Twp. of Huntington v. Marsh*, 884 F.2d 648, 653 (2nd Cir. 1989) (“a threat of irreparable injury must be proved, not assumed”).

Furthermore, the facts of the instant case mirror those in *Alcon*, where the District of Delaware found that the brand failed to prove irreparable harm and denied a motion for a permanent injunction because the order entered by the *Alcon* court resetting the ANDA approval date pursuant to 35 U.S.C. § 271(e)(4)(A) “prevents [the generic] from usurping any market share or goodwill from [the brand].” *Alcon*, 2010 WL 3081327, at *2. The *Alcon* court further found that:

any use of the patented drug by [the generic] must be private and non-commercial and, therefore, cannot irreparably harm [the brand's] full enjoyment and protection of [its] patent rights. . . . Accordingly, [the brand] cannot establish irreparable harm sufficient to satisfy the first permanent injunction factor.

Id. (internal quotations and citations omitted). *Alcon* counsels in favor of denial of Plaintiffs' Motion.

B. Plaintiffs Have Failed to Prove an Inadequate Remedy at Law.

In support of their Motion, Plaintiffs argue that “[r]emedies at law, such as monetary damages cannot compensate Plaintiffs if Defendants begin to market their generic copies of Latisse®.” (Pls.’ Br. 11-12). Plaintiffs’ conclusory assertions here are based on nothing more than attorney argument. Plaintiffs have failed to prove with expert testimony, or with any evidence at all for that matter, that monetary damages are inadequate if Defendants launch prior to expiration of the ‘029 and ‘404 patents.

But, more importantly, there is no possibility of any launch by Defendants prior to expiration of the ‘029 and ‘404 patents. “Without more, [Plaintiffs] cannot prove that an adequate remedy at law does not exist.” *Alcon*, 2010 WL 3081327, at *3.

C. The Balance of Hardships Do Not Support Entry of an Injunction.

Plaintiff assert that they have “demonstrated . . . [that they] will suffer significant and irreparable harm if Defendants are not enjoined from marketing and selling their generic copies of Latisse®.” (Pls.’ Br. 12). This is simply not true—as Defendants have explained above, this Court’s Order resetting the approval dates of Defendants’ NDAs has eliminated any possibility of harm for Plaintiffs. However, an injunction as requested by Plaintiffs would unnecessarily restrain Defendants from using their ANDA products in a non-commercial, experimental manner that does not affect Plaintiffs market share or goodwill—there is no reason for such an injunction and Plaintiffs have failed to prove any hardship that favors entry of such an injunction.

D. The Public Would Not Be Served by an Injunction.

“[B]ecause [Defendants] cannot market [their] drug during the term of the patent, the only effect of an injunction would be to deprive the public of the benefit of [Defendants’] developmental efforts.” *Alcon*, 2010 WL 3081327, at *3. Accordingly the equities favor Defendants here and Plaintiffs’ Motion should be denied. *Id.*

CONCLUSION

For the foregoing reasons, Plaintiffs’ Motion for a Permanent Injunction (10-cv-681 Doc. 211, 12-cv-321 Doc. 58) should be denied.

Respectfully Submitted,

Dated: March 11, 2013

/s/ Lyn K. Broom

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CERTIFICATE OF SERVICE

I hereby certify that I have this day electronically filed the foregoing DEFENDANTS APOTEX, SANDOZ, HI-TECH, AND WATSON'S BRIEF IN OPPOSITION TO PLAINTIFFS ALLERGAN AND DUKE'S MOTION FOR A PERMANENT INJUNCTION and accompanying documents with the Clerk of Court using the CM/ECF system, which will send notification to all parties.

This the 11th day of March, 2013.

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